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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,238	03/12/2004	Elliott Richelson	07039-126002	7520

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,238

Applicant(s)

RICHELSON ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Amendment

2. The reply filed on 9-11-06 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicants have not provided an adequate response to the double patenting rejection of claim 15 over claims 1-52 of U.S. Patent No. 6,472,209 B1. Claim 15 remains rejected for the reasons of record in the Office Action mailed 12-15-05 on the ground of nonstatutory double patenting over US Patent No. 6,472,209 B1. Applicants have not properly responded to this matter in the reply filed 4-20-06 or in the current reply filed 9-11-06.

3. The rejection of claims 15-24 and 26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-11, 13, and 17-18 of U.S. Patent No. 6,989,270 B1, is withdrawn in response to the Terminal disclaimer filed 9-11-06.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 15-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, and 21-25 of U.S. Patent No. 6,743,627 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the issued claims are drawn to a method of treating an animal comprising orally administering to said animal (or in other words, the cells of an animal) a polyamide nucleic acid oligomer containing a neutral amide backbone and containing a sequence that is complementary to a target nucleic acid under conditions wherein said polyamide nucleic acid oligomers engenders a biological response in a sequence specific manner. The instant claim differs from the issued claims to the extent that the issued claims are drawn to a method of treating "an animal" and the instant claims are drawn to a method of "treating" cells present in a mammal. This difference in claim language is merely an obvious variation of the issued claims since the instantly claimed method requires administration in a mammal, wherein said administration engenders a biological response. Therefore, the difference in scope between the issued claims and the instant claim is considered to be an obvious variation of the issued claims. Moreover, the instant claims differ from the issued claims to the extent that the instant claims do not recite wherein the polyamide neutral

oligomers are administered orally. However, the instant claims are limited to extracranial administration. However, it is clear that extracranial administration encompasses oral administration, since regulation of extracranial polypeptides via oral administration of neutral polyamide oligomers is encompassed within the scope of issued claim 7. Therefore, oral administration of neutral polyamide oligomers having a sequence complementary to a target nucleic acid also includes as an obvious alternative embodiment, extracranial administration, since this mode of delivery leads to an extracranial biological response.

6. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the full scope of the issued claims. For example issued claim 3 is drawn to the extracranial administration of a neutral polyamide nucleic acid oligomer, wherein said oligomer modulates transcription of a coding sequence, however the instant claims encompass extracranial administration of a neutral polyamide oligomer that engenders a biological response. The phrase “engenders a biological response” is anticipated by the phrase “modulates transcription of a coding sequence,” since it represents a species of the broader genus of “engendering a biological response.” This difference in claim language is merely an obvious variation of the issued claims since the both the instant claims and the issued claims are drawn to a method that comprises the administration of a polyamide to engender a biological response.

7. Moreover, in regards to claim 26, wherein a nervous system cell is treated, issued claims 21 and 23 indicate that oral administration of neutral polyamide oligomers

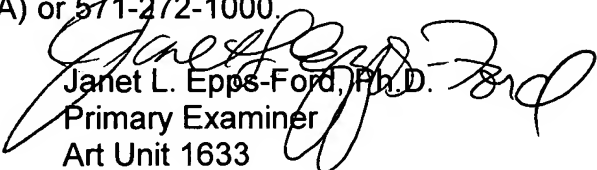
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to a mammal results in the delivery of the oligomer across a blood-brain barrier of said animal. Issued claims 21 and 23, wherein the recited method comprises delivery of oligomers across the blood-brain barrier, therefore render obvious the instant claims wherein administration of neutral polyamide oligomers result in delivery of the oligomers to a nervous system cell, since cells across the blood-brain barrier are nervous system cells.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE